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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,234	01/11/2002	Paola Elisabettini	DI-5782	8974
29200	7590	09/22/2004	EXAMINER	
BAXTER HEALTHCARE CORPORATION			CHOI, FRANK I	
RENAL DIVISION			ART UNIT	PAPER NUMBER
1 BAXTER PARKWAY			1616	
DF3-3E				
DEERFIELD, IL 60015			DATE MAILED: 09/22/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/044,234	ELISABETTINI ET AL.
	Examiner	Art Unit
	Frank I Choi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 July 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-82 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-82 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/2004 has been entered.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,11,15,16,44,52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Watanabe et al. (US Pat 5,122,516).

Watanabe et al. expressly discloses a two part composition which are stored separately in which first composition contains sodium, potassium and the second composition contains sodium and bicarbonate which is used for blood dialysis falling within the scope of applicant's claims (Column 6, lines 13-68, Columns 7-10).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980); *In re May*, 197 USPQ 601, 607 (CCPA 1978); *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive. There is nothing that precludes the same prior art reference from being used to reject claims under 102/103 inherency basis and under 103 (a) based on obviousness. Therefore, this is not a sufficient basis for overcoming the rejection herein.

Claims 1-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US Pat. 5,871,477) in view of Watanabe et al. (US Pat. 5,122,516) in view of Feriani et al. (US Pat. 4,630,727) and van Bommel et al..

Isono et al. disclose a two part dialysis composition, containing bicarbonate and electrolyte, in which a portion of the electrolyte, for example sodium, can be in the bicarbonate part where the concentration of sodium is 90 to 150 mEq/L (Column 4, lines 60-68 , Column 5, lines 1-15, Column 8-65, Column 10, lines 44-58, Column 14, lines 10-68, Column 19, lines 12-68, column 20).

Watanabe et al. teach a two part composition, the first composition which contains an acid pH adjusting agent and sodium and the second composition which contains sodium and bicarbonate, which are stored separately and used for blood dialysis (Column 6, lines 13-68, Columns 7-10). A preferred embodiment is taught in which potassium is listed as a component in first composition but not the second composition (Column 6, lines 13-68, Columns 7-10).

Feriani et al. teach a two part composition contained in a twin-chamber bag in which the first chamber is filled with a bicarbonate-containing fluid and the second chamber is filled with an acid fluid (Abstract, Figures 1,2). An embodiment is taught where potassium is listed as a component in the bicarbonate containing solution but is not listed in the acid fluid (Column 6, lines 15-44). It is taught that the composition may be used for dialysis, hemofiltration and infusion (Column 6, lines 54-55). It is taught that for safety reasons it is preferred to have the bicarbonate in the compartment which has the discharge duct to prevent the acid part from being administered to the patient unmixed (Column 7, lines 3-21).

van Bommel et al. teach that hemodialysis and continuous renal replacement therapy can use the same fluids (Pgs. 271, Table 2, 272).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a two-part composition comprising potassium in both the bicarbonate part and electrolyte part. However, the prior art amply suggests the same as it is known in the art to have two-part compositions in which potassium is contained either in the acid/electrolyte part or the bicarbonate part. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which potassium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. Further, it would have been well within the skill of one of ordinary skill in the art to have varying pH's in the bicarbonate part and acid/electrolyte part, including pH's falling within the claimed pH's, depending on the desired amounts of acid and bicarbonate in each part and the desired final pH of the mixture of the two parts. Also, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use a double chambered bag in which a first component cannot be administered to a patient without mixing with the second component for purposes of patient safety. Finally, it

would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the two-part compositions for hemofiltration, including renal replacement therapy and infusion, with the expectation that the prior art dialysate composition would be suitable for the same.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The prior art discloses that it is known to have two-part compositions in which sodium is contained in the acid/electrolyte part and the bicarbonate part. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which sodium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. See *In re Burhans*, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.). Applicant has not shown any new or unexpected results of having equimolar amounts of sodium. Further, 15-40 mmol/l falls with the range of 160 mmol/L or less. With respect to amounts of about 100 mmol/L to about 160 mmol/L it is well within the skill of one of

ordinary skill in the art, since it is disclosed that the sodium electrolyte may be in both compartments, to provide any amount of sodium including equimolar amounts, provided that the combination results in a range of 160 mmol/L or less.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

September 20, 2004



SABIHA QAZI, PH.D
PRIMARY EXAMINER